



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,230	05/08/2001	John Hamilton	111590-121 (US2)	4015

28089 7590 07/28/2003

HALE AND DORR LLP
300 PARK AVENUE
NEW YORK, NY 10022

EXAMINER

BELYAVSKYI, MICHAEL A

ART UNIT	PAPER NUMBER
----------	--------------

1644

DATE MAILED: 07/28/2003

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/851,230

Applicant(s)

HAMILTON ET AL.

Examiner

Michail A Belyavskyi

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: |

Art Unit: 1644

DETAILED ACTION

Claims 1-28 are pending.

Restriction Requirement

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
 - I. Claims 1-7 drawn to a method for ameliorating the effects of inflammation in a subject, comprising administering an agent which inhibits or otherwise antagonizes the effects of a colony-stimulating factor on cells, wherein said agent is a colony-stimulating factor receptor in soluble form, classified in Class 424, subclass 185.1.
 - II. Claims 1-7 drawn to a method for ameliorating the effects of inflammation in a subject, comprising administering an agent which inhibits or otherwise antagonizes the effects of a colony-stimulating factor on cells, wherein said agent is a binding protein of a colony-stimulating factor, classified in Class 424, subclass 184.1.
 - III. Claims 1-7 drawn to a method for ameliorating the effects of inflammation in a subject, comprising administering an agent which inhibits or otherwise antagonizes the effects of a colony-stimulating factor on cells, wherein said agent is an antibody to a colony-stimulating factor, classified in Class 424, subclass 139.1.
 - IV. Claims 1-2, 4, 8-13 and 28 drawn to a method for ameliorating the effects of inflammation in a subject, comprising administering an agent which antagonizes the effects of a colony-stimulating factor on cells and an agent which antagonize the effects of uPA wherein an agent which inhibits or otherwise antagonizes the effects of a colony-stimulating factor on cells is a colony-stimulating factor receptor in soluble form, classified in Class 424, subclass 185.1.
 - V. Claims 1-2, 4, 8-13 and 28 drawn to a method for ameliorating the effects of inflammation in a subject, comprising administering an agent which antagonizes the effects of a colony-stimulating factor on cells and an agent which antagonize the effects of uPA wherein an agent which inhibits or otherwise antagonizes the effects of a colony-stimulating factor on cells is a binding protein of a colony-stimulating factor, classified in Class 424, subclass 184.1.

Art Unit: 1644

- VI. Claims 1-2, 4, 8-13 and 28 drawn to a method for ameliorating the effects of inflammation in a subject, comprising administering an agent which antagonizes the effects of a colony-stimulating factor on cells and an agent which antagonize the effects of uPA wherein an agent which inhibits or otherwise antagonizes the effects of a colony-stimulating factor on cells is an antibody to a colony-stimulating factor, classified in Class 424, subclass 139.1.
- VII. Claims 1-2, 4, 8-13 and 28 drawn to a method for ameliorating the effects of inflammation in a subject, comprising administering an agent which antagonizes the effects of a colony-stimulating factor on cells and an agent which antagonize the effects of uPA and other inflammatory mediators produced by said cells, wherein an agent which inhibits or otherwise antagonizes the effects of a colony-stimulating factor on cells is a colony-stimulating factor receptor in soluble form, classified in Class 424, subclass 185.1.
- VIII. Claims 1-2, 4, 8-13 and 28 drawn to a method for ameliorating the effects of inflammation in a subject, comprising administering an agent which antagonizes the effects of a colony-stimulating factor on cells and an agent which antagonize the effects of uPA and other inflammatory mediators produced by said cells, wherein an agent which inhibits or otherwise antagonizes the effects of a colony-stimulating factor on cells is a binding protein of a colony-stimulating factor, classified in Class 424, subclass 184.1.
- IX. Claims 1-2, 4, 8-13 and 28 drawn to a method for ameliorating the effects of inflammation in a subject, comprising administering an agent which antagonizes the effects of a colony-stimulating factor on cells and an agent which antagonize the effects of uPA and other inflammatory mediators produced by said cells, wherein an agent which inhibits or otherwise antagonizes the effects of a colony-stimulating factor on cells is an antibody to a colony-stimulating factor, classified in Class 424, subclass 139.1.
- X. Claims 14-16, drawn to a composition comprising one or more molecules capable of antagonizing the ability of a colony-stimulating factor on cell, classified in Class 424, subclass 184.1.
- XI. Claims 14-17, drawn to a composition comprising one or more molecules capable of antagonizing the ability of a colony-stimulating factor on cell and an agent which antagonizes the effects of u-PA, classified in Class 424, subclass 184.1.

Art Unit: 1644

- XII. Claims 14-17, drawn to a composition comprising one or more molecules capable of antagonizing the ability of a colony-stimulating factor on cell and an agent which antagonizes the effects of u-PA and /or other inflammatory mediators produced by said cell, classified in Class 424, subclass 184.1.
- XIII. Claim 18, drawn to a composition comprising an antagonist of u-PA, classified in Class 424, subclass 184.1.
- XIV. Claim 18, drawn to a composition comprising an antagonist of u-PA and an antagonist of one or more other inflammatory mediators produced by cells, classified in Class 424, subclass 184.1.
- XV. Claim 19, drawn to a composition comprising immunointeractive molecules to M-CFS and GM-CSF and an antagonist of u-PA, classified in Class 424, subclass 130.1 and 184.1.
- XVI. Claim 19, drawn to a composition comprising immunointeractive molecules to M-CFS and GM-CSF and an antagonist of u-PA and an antagonist of one or more other inflammatory mediators produced by cells, classified in Class 424, subclass 130.1 and 184.1.
- XVII. Claims 20-23 and 26-27 drawn to a method for ameliorating the effects of inflammation in a subject, comprising administering an agent comprising a monocytes/macrophage interacting ligand chemically linked to an active portion, classified in Class 424, subclass 193.1.
- XVIII. Claims 24-25 drawn to an agent comprising a monocytes/macrophage interacting ligand chemically linked to an active portion, classified in Class 424, subclass 193.1.

2. Groups I-IX and XVII are different methods. These inventions are different with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

Art Unit: 1644

3. Groups X-XVI and XVIII are different products. These inventions differ with respect to their structures, physicochemical properties and mode of action which require non-coextensive searches; therefore each product is patentably distinct.

4 Groups (X /I-III); (XI/ IV-VI); (XII/VII-IX) and (XVIII/XVII) are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different X, XI, XII and XVIII can be used for crystallography, or antibody production or affinity purification in addition for a method for ameliorating the effects of inflammation in a subject.

5. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).


A telephone call was made to Lisa Wilson on 07/18/03 to request an oral election to the above restriction requirement, but did not result in an election being made.

Art Unit: 1644

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Michail Belyavskiy, Ph.D.
Patent Examiner
Technology Center 1600
July 28, 2003


CHRISTINA CHAN
SENIOR PATENT EXAMINER
TECHNOLOGY CENTER 1600